Complete Summary

GUIDELINE TITLE

Neonatal resuscitation: 2005 International Consensus Conference on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations.

BIBLIOGRAPHIC SOURCE(S)

Neonatal resuscitation. In: 2005 International Consensus Conference on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations. Circulation 2005 Nov 29;112(22 Suppl):III91-9. [118 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Neonatal asphyxiation
Cardiopulmonary arrest (cardiac arrest)

GUIDELINE CATEGORY

Management
Risk Assessment
Treatment

CLINICAL SPECIALTY

Emergency Medicine
Family Practice
Internal Medicine
Obstetrics and Gynecology
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Emergency Medical Technicians/Paramedics
Health Care Providers
Hospitals
Nurses
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To provide guidance on neonatal cardiopulmonary resuscitation

TARGET POPULATION

Neonatal infants requiring resuscitation

INTERVENTIONS AND PRACTICES CONSIDERED

Management

1. Initial resuscitation
2. Use of supplementary oxygen
3. Tracheal suctioning for meconium
4. Establishing effective ventilation
    - Assisted ventilation devices (self-inflating bag, flow inflating bag, T-piece mechanical device)
    - Laryngeal mask airway
5. Ventilation strategies for preterm infants
6. Confirmation of tracheal tube placement
    - Use of exhaled CO_2 detectors
7. Pharmacological agents
    - Epinephrine
    - Crystalloids and colloids
    - Naloxone (not recommended as part of initial resuscitation of newborns)
8. Supportive therapy
    - Maintenance of body temperature
9. Postresuscitation management
    - Prevention of hyperthermia
    - Therapeutic hypothermia (considered but not recommended routinely)
    - Blood glucose monitoring and treatment
10. Withholding and discontinuing resuscitation

MAJOR OUTCOMES CONSIDERED

- Neonatal mortality and morbidity rates
- Long-term outcomes
- Neurological outcomes

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

All reviewers were instructed to search their allocated questions broadly. Reviewers documented their search strategies to ensure reproducibility of the search. The minimum electronic databases searched included the Cochrane database for systematic reviews and the Central Register of Controlled Trials (http://www.cochrane.org/), MEDLINE (http://www.ncbi.nlm.nih.gov/PubMed/), EMBASE (www.embase.com), and the master reference library collated by the American Heart Association (AHA). To identify the largest possible number of relevant articles, reviewers were also encouraged to perform hand searches of journals, review articles, and books as appropriate.

The reviewers documented the mechanism by which studies relevant to the hypothesis were selected. Specific study inclusion and exclusion criteria and study limitations were documented. Inclusion of all relevant evidence (from animal and manikin/model studies as well as human studies) was encouraged.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Level 1: Randomized clinical trials or meta-analyses of multiple clinical trials with substantial treatment effects

Level 2: Randomized clinical trials with smaller or less significant treatment effects

Level 3: Prospective, controlled, nonrandomized cohort studies

Level 4: Historic, nonrandomized cohort or case-control studies

Level 5: Case series; patients compiled in serial fashion, control group lacking

Level 6: Animal studies or mechanical model studies

Level 7: Extrapolations from existing data collected for other purposes, theoretical analyses

Level 8: Rational conjecture (common sense); common practices accepted before evidence-based guidelines

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

A worksheet template was provided with step-by-step directions to help the experts document their literature review, evaluate studies, and determine levels of evidence. When possible, 2 expert reviewers were recruited to undertake independent evaluations for each topic.

Assessing the Quality of Evidence

In this step reviewers were asked to determine the level of evidence of relevant studies (Step 2A), assess the quality of study research design and methods (Step 2B), determine the direction of results (Step 2C), and cross-tabulate assessed studies (Step 2D).

The levels of evidence used for the 2005 consensus process were modified from those used in 2000. In many situations summary conclusions were based on lower levels of evidence because human clinical trial data was not available. The reviewers assessed the quality of research design and methods and allocated each study to 1 of 5 categories: excellent, good, fair, poor, or unsatisfactory. Studies graded as poor or unsatisfactory were excluded from further analysis.

Reviewers evaluated the direction of the study results as supportive, neutral, or opposed and then depicted the data in 1 of 2 grids. The grids were 2-dimensional, showing quality and levels of evidence. The reviewers completed a Supporting Evidence grid and a Neutral or Opposing Level of Evidence grid.

Controversies Encountered

Studies on Related Topics (Level of Evidence [LOE] 7)

Many reviewers identified studies that answered related questions but did not specifically address the reviewer's initial hypothesis. Examples include the extrapolation of adult data for pediatric worksheets and extrapolation of the results of glucose control in critically ill patients to the postresuscitation setting. Worksheet reviewers were instructed to clearly designate evidence that represented extrapolations. Reviewers could designate such studies as LOE 7, or they could assign a level of evidence based on the study design but include terms such as "extrapolated from" with specific relevant details in the draft consensus on science statements to indicate clearly that these were extrapolations from data collected for other purposes.

Animal Studies and Mechanical Models

Animal studies can be performed under highly controlled experimental conditions using extremely sophisticated methodology. Irrespective of methodology, all animal studies and all studies involving mechanical models (e.g., manikin studies) were classified as LOE 6. Specific details about these studies (including methodology) are included in the summary of science where appropriate.

Studies Evaluating Diagnosis or Prognosis

The default levels of evidence used for the 2005 consensus process were not designed for the review of studies that evaluate diagnosis or prognosis. For these studies other methods of assigning levels of evidence were considered (such as those proposed by the Oxford Centre for Evidence-Based Medicine [http://www.cebm.net/]). Worksheet reviewers planning to include alternative levels of evidence were asked to define such levels clearly and to retain the default levels of evidence.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus
Expert Consensus (Consensus Development Conference)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Worksheet reviewers created a summary of the science. In the summary format reviewers were encouraged to provide a detailed discussion of the evidence, including the outcomes evaluated and the strengths and limitations of the data.

The final step in the science summary process was the creation of draft consensus on science statements and treatment recommendations. Statement templates were provided to standardize the comprehensive summary of information. Elements of the consensus on science statement template included the specific intervention or assessment tool, number of studies, levels of evidence, clinical outcome, population studied, and the study setting. Elements of the treatment recommendation template included specific intervention or assessment tool, population and setting, and strength of recommendation.

The statements drafted by the reviewers in the worksheets reflect the recommendations of the reviewers and may or may not be consistent with the conclusions of the 2005 Consensus Conference.

All 380 participants at the 2005 Consensus Conference received a copy of the worksheets on CD-ROM. Expert reviewers presented topics in plenary, concurrent, and poster conference sessions. Presenters and participants then debated the evidence, conclusions, and draft summary statements. Each day the most controversial topics from the previous day, as identified by the task force chairs, were presented and debated in one or more additional sessions. The International Liaison Committee on Resuscitation (ILCOR) task forces met daily during the conference to discuss and debate the experts' recommendations and develop interim consensus science statements. Each science statement summarized the experts' interpretation of all the relevant data on a specific topic. Draft treatment recommendations were added if a consensus was reached.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Completed worksheets were posted on the Internet for further review. The initial process involved posting the worksheet to a password-protected area of the American Heart Association Intranet (accessible to worksheet reviewers). In December 2004 the completed worksheets were posted on an Internet site that could be accessed by the public for further review and feedback before the 2005 Consensus Conference in Dallas (www.C2005.org).

Wording of science statements and treatment recommendations was refined after further review by International Liaison Committee on Resuscitation (ILCOR) member organizations and the international editorial board. This format ensured that this final document represents a truly international consensus process.

The manuscript was ultimately approved by all ILCOR member organizations and by an international editorial board. The American Heart Association (AHA) Science Advisory and Coordinating Committee and the editor of Circulation obtained peer reviews of this document before it was accepted for publication. The document is being published simultaneously in Circulation and Resuscitation, although the version in Resuscitation does not include the sections on stroke and first aid.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Initial Resuscitation

Supplementary Oxygen

Supplementary Oxygen Versus Room Air

There is currently insufficient evidence to specify the concentration of oxygen to be used at initiation of resuscitation. After initial steps at birth, if respiratory efforts are absent or inadequate, lung inflation/ventilation should be the priority. Once adequate ventilation is established, if the heart rate remains low, there is no evidence to support or refute a change in the oxygen concentration that was initiated. Rather the priority should be to support cardiac output with chest compressions and coordinated ventilations. Supplementary oxygen should be considered for babies with persistent central cyanosis. Some have advocated adjusting the oxygen supply according to pulse oximetry measurements to avoid hyperoxia, but there is insufficient evidence to determine the appropriate oximetry goal because observations are confounded by the gradual increase in oxyhemoglobin saturation that normally occurs following birth. Excessive tissue oxygen may cause oxidant injury and should be avoided, especially in the premature infant.

Peripartum Management of Meconium

Intrapartum Suctioning

Routine intrapartum oropharyngeal and nasopharyngeal suctioning for infants born with meconium-stained amniotic fluid is no longer recommended.

Tracheal Suctioning

Meconium-stained, depressed infants should receive tracheal suctioning immediately after birth and before stimulation, presuming the equipment and expertise is available. Tracheal suctioning is not necessary for babies with meconium-stained fluid who are vigorous.

Ventilation Strategies

Initial Breaths

Establishing effective ventilation is the primary objective in the management of the apneic or bradycardic newborn infant in the delivery room. In the bradycardic infant, prompt improvement in heart rate is the primary measure of adequate initial ventilation; chest wall movement should be assessed if heart rate does not improve. Initial peak inflating pressures necessary to achieve an increase in heart rate or movement of the chest are variable and unpredictable and should be individualized with each breath. If pressure is being monitored, an initial inflation

pressure of 20 cm H_2O may be effective, but a pressure $\geq$30 to 40 cm H_2O may be necessary in some term babies. If pressure is not being monitored, the minimal inflation required to achieve an increase in heart rate should be used. There is insufficient evidence to recommend optimal initial or subsequent inflation times.

Assisted Ventilation Devices

A self-inflating bag, a flow-inflating bag, or a T-piece mechanical device designed to regulate pressure as needed can be used to provide bag-mask ventilation to a newborn.

Laryngeal Mask Airway (LMA)

The LMA may enable effective ventilation during neonatal resuscitation if bag-mask ventilation is unsuccessful and tracheal intubation is unsuccessful or not feasible. There is insufficient evidence to recommend use of the LMA as the primary airway device during neonatal resuscitation or in the settings of meconium-stained amniotic fluid, when chest compressions are required, or for the delivery of drugs into the trachea.

Ventilation Strategies for Preterm Infants

Providers should avoid creation of excessive chest wall movement during ventilation of preterm infants immediately after birth. Although measured peak inflation pressure does not correlate well with volume delivered in the context of changing respiratory mechanics, monitoring of inflation pressure may help provide consistent inflations and avoid unnecessarily high pressures. If positive-pressure ventilation is required, an initial inflation pressure of 20 to 25 cm H_2O is adequate for most preterm infants. If prompt improvement in heart rate or chest movement is not obtained, then higher pressures may be needed.

Use of Continuous Positive Airway Pressure (CPAP) or Positive End-Expiratory Pressure (PEEP)

There is insufficient data to support or refute the routine use of CPAP during or immediately after resuscitation in the delivery room.

Exhaled Carbon Dioxide (CO_2) Detectors to Confirm Tracheal Tube Placement

Tracheal tube placement must be confirmed after intubation, especially in infants with a low heart rate that is not rising. Exhaled CO_2 detection is useful to confirm tracheal tube placement. During cardiac arrest, if exhaled CO_2 is not detected, tube placement should be confirmed with direct laryngoscopy.

Medications

Epinephrine

Route and Dose of Epinephrine

Despite the lack of human data, it is reasonable to continue to use epinephrine when adequate ventilation and chest compressions have failed to increase the heart rate to >60 beats per minute. Use the intravenous (IV) route for epinephrine as soon as venous access is established. The recommended IV dose is 0.01 to 0.03 mg/kg. If the tracheal route is used, give a higher dose (up to 0.1 mg/kg). The safety of these higher tracheal doses has not been studied. Do not give high doses of intravenous epinephrine.

Volume Expansion

Crystalloids and Colloids

In consideration of cost and theoretical risks, an isotonic crystalloid solution rather than albumin should be the fluid of choice for volume expansion in neonatal resuscitation.

Other Drugs

Naloxone

Naloxone is not recommended as part of the initial resuscitation of newborns with respiratory depression in the delivery room. Before naloxone is given, providers should restore heart rate and color by supporting ventilation. The preferred route should be IV or intramuscular. Tracheal administration is not recommended. There is no evidence to support or refute the current dose of 0.1 mg/kg.

Supportive Therapy

Temperature Control

Maintenance of Body Temperature

Very low birth weight preterm babies remain at risk for hypothermia. Consider the use of plastic bags or plastic wrapping under radiant heat as well as standard techniques to maintain temperature. All initial resuscitation steps, including intubation, chest compression, and insertion of lines, can be performed with these temperature-controlling interventions in place.

Postresuscitation Management

Temperature

Hyperthermia

The goal is to achieve normothermia and to avoid iatrogenic hyperthermia in babies who require resuscitation.

Therapeutic Hypothermia

There is insufficient data to recommend the routine use of systemic or selective cerebral hypothermia after resuscitation of infants with suspected asphyxia. Further clinical trials are needed to confirm that treatment with cooling is beneficial, to identify infants who will benefit most, and to determine the most effective method and timing of cooling.

General Supportive Care

Glucose

Based on available evidence, the optimal range of blood glucose concentration to minimize brain injury following asphyxia and resuscitation cannot be defined. Infants requiring resuscitation should be monitored and treated to maintain glucose in the normal range.

Timing of Cord Clamping

No recommendation can be made about the timing of cord clamping when resuscitation is required.

Withholding or Discontinuing Resuscitative Efforts

A consistent and coordinated approach to individual cases by obstetric and neonatal teams and parents is an important goal. Not starting resuscitation and discontinuation of life-sustaining treatment during or after resuscitation are ethically equivalent, and clinicians should not be hesitant to withdraw support when functional survival is highly unlikely. The following guidelines must be interpreted according to current regional outcomes and societal principles:

- When gestation, birth weight, or congenital anomalies are associated with almost certain early death and an unacceptably high morbidity is likely among the rare survivors, resuscitation is not indicated. Examples from the published literature from developed countries include:
    - Extreme prematurity (gestational age <23 weeks or birth weight <400 g)
    - Anomalies such as anencephaly and confirmed trisomy 13 or 18
- In conditions associated with a high rate of survival and acceptable morbidity, resuscitation is nearly always indicated.
- In conditions associated with uncertain prognosis, when there is borderline survival and a relatively high rate of morbidity, and where the burden to the child is high, the parents' views on starting resuscitation should be supported.

If there are no signs of life after 10 minutes of continuous and adequate resuscitative efforts, it may be justifiable to stop resuscitation.

CLINICAL ALGORITHM(S)

The International Liaison Committee on Resuscitation (ILCOR) Neonatal Flow Algorithm is provided in the original guideline document.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate cardiopulmonary resuscitation in neonatal infants to increase survival rates

POTENTIAL HARMS

- Naloxone has been associated with cardiac arrhythmias, hypertension, and noncardiogenic pulmonary edema in adolescents and adults, especially when high doses have been used.
- Naloxone given to a baby born to an opioid-addicted mother has been associated with seizures.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This document summarizes current evidence for the recognition and response to sudden life-threatening events, particularly sudden cardiac arrest in victims of all ages. The broad range and number of topics reviewed and the inevitable limitations of journal space require succinctness in science statements and, where recommendations were appropriate, brevity in treatment recommendations. This is not a comprehensive review of every aspect of resuscitation medicine; some topics were omitted if there was no evidence or no new information.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Neonatal resuscitation. In: 2005 International Consensus Conference on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations. Circulation 2005 Nov 29;112(22 Suppl):III91-9. [118 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Nov 29

GUIDELINE DEVELOPER(S)

American Heart Association - Professional Association

SOURCE(S) OF FUNDING

American Heart Association

GUIDELINE COMMITTEE

International Liaison Committee on Resuscitation (ILCOR)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

A robust conflict of interest policy was developed to ensure full disclosure of potential conflicts and to protect the objectivity and credibility of the evidence evaluation and consensus development process. This policy is described in detail

in an editorial companion document (see "Availability of Companion Documents" field). Representatives of manufacturers and industry did not participate in this conference.

Potential conflicts of interest of the editorial board are listed in Appendix 3 of the original guideline document (see "Availability of Companion Documents" field). Potential conflicts of interest of the worksheet authors are noted in the worksheets and can be accessed through the links to the worksheets contained in the original guideline document. All 380 attendees were required to complete forms in order to document their potential conflicts of interest. Most attendees were also worksheet authors. The information from the conflict of interest forms completed by all conference attendees, including worksheet authors, can also be accessed at the website http://circ.ahajournals.org/content/vol112/22_suppl/#APPENDIX. Readers of the print version can also access the statements at the American Heart Association website: www.C2005.org.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Heart Association Web site.

Print copies: Available from the American Heart Association, Public Information, 7272 Greenville Ave, Dallas, TX 75231-4596; Phone: 800-242-8721

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Introduction. 2005 International Consensus Conference on Cardiopulmonary Consensus Conference on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations. Circulation 2005 Nov 29;112(22 Supplement):III-1-III-4.
- The evidence evaluation process for the 2005 International Consensus Conference on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations. Circulation 2005 Nov 29;112(22 Supplement):III-128-III-130.
- Conflict of interest management before, during, and after the 2005 International Consensus Conference on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations. Circulation 2005 Nov 29;112(22 Supplement):III-131-III-132.
- Controversial topics from the 2005 International Consensus Conference on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations. Circulation 2005 Nov 29;112(22 Supplement):III-133-III-136.
- Appendix 1: Worksheet topics and authors. Circulation 2005 Nov 29;112(22 Supplement):B1-B14.

- Appendix 3: Conflict of interest for editors, editorial board, special contributors and reviewers, and honorees. Circulation 2005 Nov 29;112(22 Supplement):B16-B18.
- Interdisciplinary topics: 2005 International Consensus Conference on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations. Circulation 2005 Nov 29;112(22 Supplement):III-100-III-108.

Electronic copies: Available from the American Heart Association Web site.

Print copies: Available from the American Heart Association, Public Information, 7272 Greenville Ave, Dallas, TX 75231-4596; Phone: 800-242-8721

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on February 6, 2006. The information was verified by the guideline developer on March 7, 2006.

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